

The use of bone block allografts in sinus augmentation, followed by delayed implant placement: A case series

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Abstract

Purpose: This article reports the clinical outcomes observed in a large number of patients receiving block bone allograft used for sinus augmentation and delayed implant placement. **Patients and Methods:** In total, 28 patients (13 males) with a mean age of 49.8 ± 10.1 years (range: 33-67 years) were included in this case series. All selected patients suffered from severe alveolar ridge atrophy in the posterior maxilla and required bone augmentation procedures, followed by implant placement after 6 months. All patients were followed for 18 months after the grafting, with scheduled monthly visits and/or more frequent visits if required. The survival rates for both the bone blocks and placed implants were then evaluated. **Results:** A total of 42 blocks and 90 implants were placed. Only one bone graft and 5 implants failed; the survival rate was 97.2% and 95.5% for the bone grafts and implants, respectively. The graft failed due to the onset of post-surgical infectious sinusitis, while in some patients' implants showed absence of osteointegration at the end of the healing phase. Of note, all failed implants were observed in heavy smokers; in all other patients, blocks and implants were successful. **Conclusions:** This preliminary case series suggests that the grafting of bone allograft followed by delayed implant placement may be a promising strategy for sinus augmentation. More extended and larger follow-up studies are needed to confirm this preliminary data.

Keywords: Grafting, implants, sinus block

Introduction

A fundamental prerequisite for implant placement is the presence of adequate bone quantity. Frequently in the posterior edentulous maxilla, the available residual alveolar ridge is insufficient for the placement of dental implants due to alveolar bone resorption, pneumatization of the maxillary sinus, or indeed a combination of both. Therefore, a bone augmentation procedure becomes an essential step in the completion of the treatment. Of a number of standard augmentation procedures used in case of extreme pneumatization of the maxillary sinus is the lateral approach. This technique involves the elevation of the sinus membrane from the floor of the maxillary sinus in order to allow the placement of bone graft, autogenous

bone or a mixture of these materials. Tatum first reported this technique using a modified Cadwell Luc approach,^[1] but several modifications have been made since these early reports to the surgical technique and the material used.^[2]

As far as the graft is concerned, autogenous bone was largely used in early sinus augmentation techniques.^[3] However, autogenous bone has several drawbacks such as the need for a second surgical site, donor site morbidity and longer hospitalization period.^[4] Furthermore, a high percentage of infections and a rapid and unpredictable resorption may invalidate long term results.^[4] Finally, several reviews, indicate that the exclusive use of autogenous bone does not improve the survival rate of the implant.^[5] Since sinus augmentation is an elective procedure, the reduction of patient morbidity to a minimum is mandatory. Consequently, the use of bone substitutes such as allograft and xenograft materials has progressively gained the attention of clinicians. Both xenograft and alloplast materials have shown predictable and successful results.^[6] Mineralized human bone allograft was recently introduced and showed promising results in periodontal and bone regeneration.^[6] This grafting material is a bone-derived product which is harvested from cadavers, solvent dehydrated and processed, and then sterilized. It has been demonstrated that such material processing reduces the risk of infection transmission to negligible.^[7]

Such grafting material can be used in the form of bone-blocks (cancellous or corticocancellous) or bone-particles in sinus floor augmentation procedures. Boyne and James first reported the surgical technique using an inlay autogenous bone graft in 1980.^[8] Their report was followed by studies^[9]

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Access this article online	
Quick Response Code:	Website: www.contemporarydentistry.org
	DOI: 10.4103/0976-237X.111587

using autogenous bone in the form of blocks. Some of these studies used the one-step technique with simultaneous sinus elevation and implant insertion, while others employed the two-step technique with implant insertion after an adequate healing time. The question whether simultaneous implant placement may be favorable in such an intervention is still under debate. A point in favor of this approach is the smaller number of surgical interventions for the patient, though a complete healing of the graft could improve the survival rate of the implants.

Despite the amount of clinical investigations to evaluate the different modalities and materials used in sinus floor elevation followed by implant placement, what the outcomes of the different grafts used and the best time for subsequent implant placement are is still controversial. Therefore, the aim of this study is to describe the clinical outcomes observed in a large group of patients receiving bone blocks allograft used for sinus augmentation when a delayed implant placement approach was used.

Patients and Methods

This study considered a case series of patients who were operated on using bone blocks for sinus augmentation and a delayed implant placement.

Bone graft preparation

Bone grafts were prepared using the same procedure as a previous similar study, conducted by Barone *et al.*^[9] The bone tissue collected from Bone Banks (Banca dei Tessuti Treviso Italy) and Emilia Romagna (Rizzoli Hospital, Bologna, Italy) was fractioned in segments of different dimensions, and then washed in sterile solution. Graft safety was evaluated via several microbiological and immunological tests, including the presence of anti-human immunodeficiency virus, Human cirrhosis virus (HCV), treponema, (CMV) cito megalovirus and toxoplasma antigens and antibodies. Decontamination of bone blocks was ensured by washing them in an antibiotic solution (vancomycin 100 µg/mL; polymyxine 100 µg/mL; ceftazidime 240 µg/mL; lincomycin 120 µg/mL in a Roswell Park Memorial Institute RPMI 1640 medium) into sterile boxes for 24 h at 4°C. After the antibiotic decontamination, bone blocks were stored at < 80°C in sterile envelopes.

Before being distributed, the blocks were washed with > 500 ml of physiologic solution (at least 500 ml) and placed in a sterile box, which was then sealed in a sterile envelope surrounded by ice cubes, maintaining a temperature of between + 2°C and + 10°C for at least 48 h. The bone tissue can be preserved at + 4°C temperature for 7 days.

Patient population

This analysis was conducted at the Istituto Stomatologico Tirreno (Ospedale Versilia, Lido di Camaiore, Italy) between March 2006 and June 2008. Versilia Hospital committee

approved the protocol. In total, 28 patients (13 males) with a mean age of 49.8 ± 10.1 years (range: 33-67 years) were included in the present analysis. Table 1 summarizes the smoking habits and the medical status of the evaluated patients. All patients required bone augmentation due to severe alveolar ridge atrophy (residual alveolar ridge between 2 mm and 4 mm high) and were scheduled for homologous bone graft and delayed titanium implants placement. Teeth extractions were performed at least 8 weeks before the surgical procedure.

All patients were required to be in overall healthy systemic condition, without any disease that would contraindicate reconstructive bone surgery. Patients were excluded if they presented any of the following conditions: Immune system diseases; pulmonary, renal, or severe cardiovascular diseases; blood diseases; tumors and neoplasms; hepatitis; drug abuse; chemotherapy; or radiotherapy. All procedures were explained to the patients before surgery; patients signed a written informed consent before being included in the analysis.

Pre-operative assessment

Each case was accurately evaluated by the same trained clinician. In particular, an examination of diagnostic casts was performed in order to assess the interarch relationship; moreover, panoramic radiographs and computed tomography scans were obtained for each patient. A full periodontal and endodontic assessment was also performed. After these analyses, appropriate dental treatments were prescribed, if necessary, to make the oral environment more favorable to wound healing. Two days before surgery, rinses with chlorhexidine digluconate 0.2% (3 times a day) were prescribed.

Surgical treatment

All surgical procedures were performed by the same trained clinician. Homologous blocks were removed from the refrigerator and soaked in sterile saline solution approximately 30 min before surgery. Patients underwent local anesthesia with articaine chlorhydrate and adrenaline (1:100,000); amoxicillin (2 g) was also administered 1 h before surgery. Sedation was induced 30 min before surgery via the administration of diazepam (20 mg). Patients were instructed to rinse their mouths with chlorhexidine for 2 min prior to surgery.

All surgeries were undertaken by the two surgeons (Antonio Barone and Ugo Covani) and their surgical teams. All the patients were treated with the same surgical technique consisting of sinus floor augmentation via a lateral approach^[9] (Barone *et al.*, 2005) without the use of osteotomes. Briefly, a mucoperiosteal flap was elevated exposing the lateral bone wall of the maxillary sinus, a modification of the conventional lateral wall approach was used to perform the osteotomy to access the sinus membrane [Figure 1].

Table 1: Medical/smoking status and bone maxillary reconstructive surgery outcome in the 28 patients evaluated

Patient no.	Age (year)	Gender	Smoking	Medical status	Fixation devices	No. of blocks	Block failures	No. of implants	Implant failures	Reasons for block/implant failure
1	33	F	-	-	-	1	-	2	-	
2	45	F	Yes	-	Yes	1	-	1	-	
3	39	F	-	-	-	1	-	2	-	
4	60	M	-	Hypertension	-	1	-	2	-	
5	43	F	Yes	-	-	1	-	2	-	
6	45	F	-	-	Yes	2	-	6	-	
7	56	M	Yes	-	Yes	2	-	6	-	
8	57	F	Yes	-	Yes	2	-	5	-	
9	42	F	-	-	-	1	1	-	-	Post-surgical infectious sinusitis 4 weeks after grafting
10	51	F	Yes	-	-	2	-	6	3	Implants with signs of mobility
11	58	M	Yes	Hypertension	-	1	-	2	2	Implants with signs of mobility
12	52	M	-	-	-	1	-	2	-	
13	56	M	Yes	-	-	1	-	1	-	
14	54	M	Yes	-	-	2	-	6	-	
15	35	M	-	-	-	1	-	1	-	
16	67	F	-	-	-	2	-	4	-	
17	64	M	Yes	-	-	2	-	4	-	
18	54	F	Yes	-	Yes	1	-	2	-	
19	48	F	-	-	-	2	-	6	-	
20	46	M	-	-	-	2	-	4	-	
21	48	F	Yes	-	Yes	2	-	4	-	
22	60	M	-	-	Yes	2	-	4	-	
23	29	M	-	-	-	1	-	1	-	
24	37	F	Yes	-	-	1	-	2	-	
25	56	M	Yes	-	-	1	-	3	-	
26	38	M	-	-	-	2	-	2	-	
27	64	F	Yes	-	Yes	2	-	6	-	
28	56	F	-	Hypertension	Yes	2	-	4	-	

A bone scraper (Safe scraper®, Meta corp. Remigia, Italy) was used to harvest autologous cortical bone and to reduce the lateral bone thickness, allowing an easy access to the sinus membrane with ultrasound (Piezosurgery, Mectron, Genova, Italy). Subsequently, the sinus mucosa was carefully dissected and elevated using mucosal sinus elevators, and the bony wall was gently inserted inside the sinus cavity to form the roof for the bone blocks. Finally, the floor of the maxillary sinus was prepared with a round steel bur to allow easy adaptation of the allograft bone blocks [Figure 2]. The size and shape of the block needed for sinus augmentation were evaluated. If necessary, the recipient site underwent recontouring to improve graft adaptation. The recipient site was also perforated with a fissure bur to induce bleeding and promote the revascularization of the graft. Then the block was inserted and adapted to the sinus cavity; all sharp angles were smoothed in order to avoid perforations of the overlying flap. Additional cancellous chips were detached from the

block and placed at the boundary of the grafts as necessary, to fill any gap between the grafts and the recipient site. All the grafts were positioned over the recipient site with the endosteal side facing the cortical bone. The blocks allograft were stabilized on the residual ridge with self-tapping screws (Cizeta, Milan, Italy) until the head reached the surface of the bone allografts [Figure 5]. Periosteal fenestration was performed at the base of the buccal flap to obtain a tension-free adaptation of the wound margins, if required. The flap was then sutured with a resorbable suture.

Post-operative procedures

The following post-surgical procedures were prescribed: Antibiotic prophylaxis with amoxicilline 2 g/day for 6 days after surgery; pain control with ibuprofene 600 mg/day for the same period, or as necessary. Patients were also instructed to use a chlorhexidine 0.2% mouthwash twice daily for 21 days. Sutures were removed 2 weeks after surgery.

Implant placement

The implants (Intralock International, Salerno, Italy) were placed 6 months after the consolidation of the grafted sites [Figure 3]. An alveolar crest incision was made and mucoperiosteal flaps were elevated to expose the sites for implant placement. The fixation screws were removed, the implant sites were prepared, and the implants were placed using a surgical guide. All the implants in this study were inserted at the alveolar crest level and showed good primary stability. The flaps were subsequently closed with silk sutures.

Follow-up and study evaluations

All patients were followed for 28 months after the grafting, with scheduled monthly visits and/or more frequent visits if required. All follow-up visits were conducted by the same trained operator. The survival rate of bone blocks was evaluated at the implant placement. A bone graft was considered to be successful if the following criteria were met: (1) absence of

graft exposure and post-operative infection; (2) incorporation of the graft with the recipient site; and (3) absence of bone radiolucency. The survival rate of implants was evaluated at the end of the healing phase, i.e., 6 months after the implant placement [Figures 6 and 7]. Implants without signs of mobility, without reported pain or discomfort on pressure, and exhibiting radiographic evidence of osseointegration were considered survivals, whereas all implants not fulfilling these criteria were considered as failures and replaced [Figures 4 a and b].

Results

A total of 42 block allografts were used, most patients received a monolateral graft [Table 1]. One block failed in a female patient as a result of the onset of sinus infection 4 weeks after the grafting. The failed block was removed and was replaced by another block allograft after eradication of sinusitis with antibiotic treatment. No further sequelae were reported in this patient after the second grafting. The overall survival rate of the homologous blocks was 97.2%.

In total, 90 implants were inserted in the 41 homologous successful blocks. Five implants failed in two different patients, with a survival rate of 95.5%. In detail, 3 implants failed in a female smoker due to mobility at the end of the healing phase, while two other implants failed in a male smoker, who was affected by hypertension, for the same

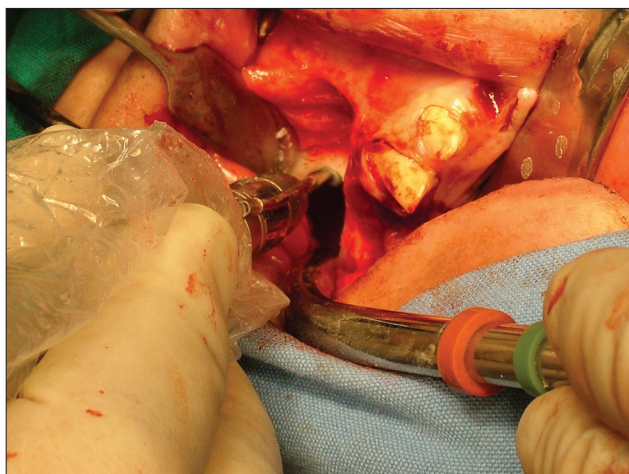


Figure 1: After the flap elevation a trap door has been created using a bur. The dimensions of the door were carefully evaluated considering the need of bone blocks placement

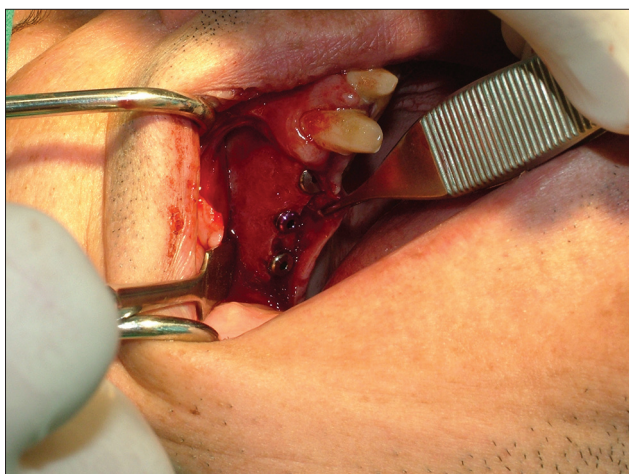


Figure 3: This picture shows the placement of the implants. They were placed 6 months after the consolidation of the grafted sites

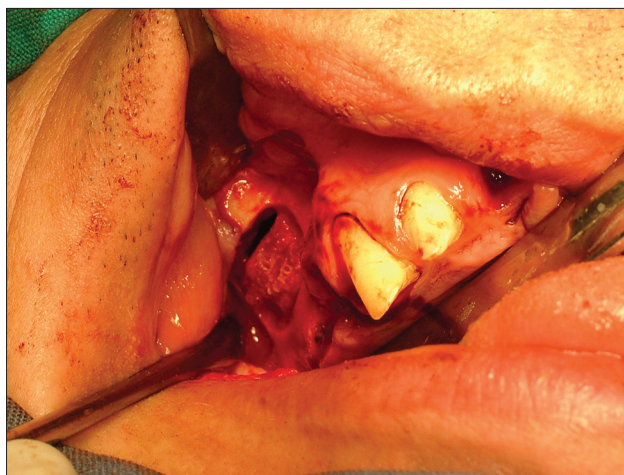


Figure 2: This image shows the placement of a bone block into the sinus cavity. Sharp edges and corners were carefully rounded before the insertion in the sinus cavity



Figures 4 a and b: These images illustrate the final rehabilitation on full arch implants



Figure 5: The radiographic images shows the stabilization of bone blocks on the residual ridge with self-tapping screws

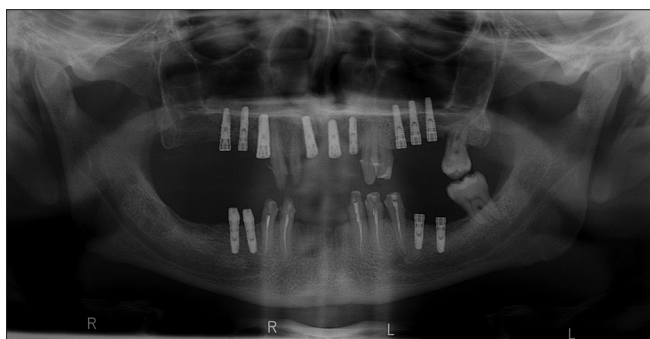


Figure 6: X-rays have been carried out at the end of the healing period. all implants exhibiting radiographic evidence of osseointegration were loaded

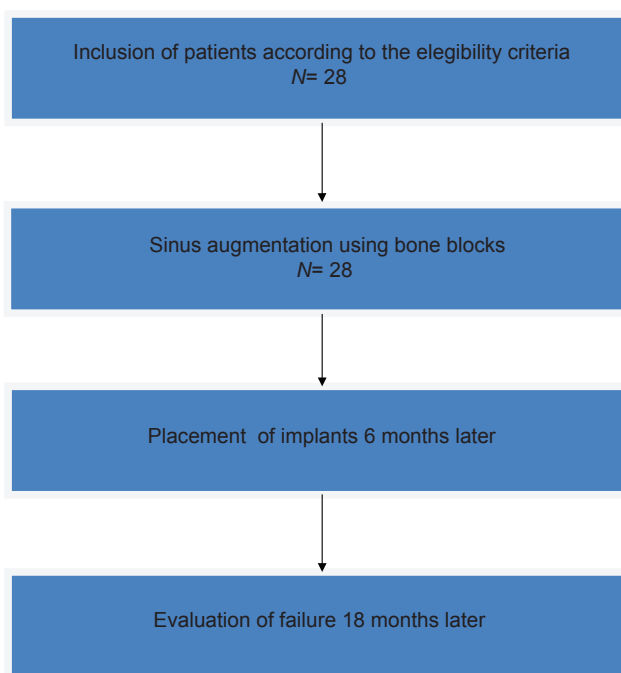


Figure 7: An additional radiological evaluation has been carried out after prosthetic rehabilitation

reason and at the same time-point [Table 1]. All failed implants were removed and replaced. In all other patients, blocks and implants were judged as successful, and no implant failures were observed during the follow-up period.

Discussion

A large number of systematic reviews have indicated that sinus floor augmentation is one of the most reliable procedures in pre-prosthetic surgery and nowadays, this method is routinely used in the treatment of patients with severe atrophic posterior maxilla. Current scientific literature does not provide a high level of evidence for the selection of autologous bone, allograft bone or xenograft biomaterials



Flowchart 1

as ideal grafts in sinus augmentation. Chaushu *et al.* first evaluated the bone formation after placement of allograft bone blocks in sinus augmentation.^[10] They concluded that this type of graft is biocompatible and osteoconductive and permits new bone formation.^[10] Other studies validated the idea that particulated mineralized bone allografts are able to promote bone formation in sinus augmentation procedures both alone and in combination with autogenous bone. Finally, it has been suggested that homologous bone may be associated with lower morbidity, shorter surgical times and less distress to the patient when compared with other bone substitutes used in clinical practice.

The present case series first reports the clinical outcomes of patients receiving fresh-frozen bone block allografts used in sinus augmentation and followed by a delayed implant placement. The decision to delay the implant placement was taken in order to obtain a complete healing of the graft and as a consequence, this improved the survival rate of the implants.

Overall, only 2.8% of grafts corresponding to one block and 5 implants failed over a 28-month period after the grafting with homologous bone. Such complication was due to infection of the graft, and subsequent post-surgical sinusitis. This event can arise after sinus augmentation. It has been demonstrated that the placement of bone allografts is more technique sensitive than autograft, and thereby, the allografts need a meticulous surgical technique and follow-up. Therefore this single failure could be due to an inaccurate preparation of the graft, inducing, as a

consequence, problems in vascularization of the same graft and thus the onset of sinusitis.

The scientific literature does not unfortunately provide any similar studies with which to compare our results. However, other authors described slightly higher percentages of complications when cancellous bone blocks were used in ridge augmentations procedures.^[10]

A large number of review and metanalysis has been carried out on this topic, concluding that several parameters can influence the success of implants and sinus graft including, implant surface, biomaterial, simultaneous or staged approach, membrane coverage.^[7]

Regarding the biomaterial, the scientific literature advanced the question whether bone substitutes or autogenous bone were better for this procedure. Donor site morbidity was observed as a major concern for the use of autologous bone, whereas some bone substitutes show an high percentage of re-absorption with re-pneumatization of sinus cavity.^[7] Although, literature lacks studies about allografts materials Chaushu *et al.* observed that new bone formation (26%) after sinus augmentation with cancellous bone blocks, was similar to the vital bone proportion of pristine bone in the posterior maxilla (23-28%)-as observed in previous studies.^[10]

Scientific literature does not report clinical advantages in using a delayed or simultaneous approach and indicates that the residual height of alveolar ridge has to be considered the parameter for the decision.^[7]

However, in our opinion, the delayed placement of implants could have allowed for better bone healing in the augmented area thereby increasing the possibilities of a positive osteointegration of the implants. Moreover, at implant placement the surgical trauma may have stimulated an immediate healing response, similar to that of the native bone, and therefore produced a better outcome.

Most of studies concluded that modified implant surfaces are significantly better in augmented sinus. The survival rate of implants can be defined as implants remaining *in situ* during the entire study follow-up. A review of 48 studies where more than 10,000 implants were placed in a simultaneous approach indicated a survival rate of 90.1% after 3 years.^[11] In this research, a survival rate of 95.5% (28 months) was observed at the end of the follow-up period^[11] using modified titanium implant surface. It is possible that this parameter as well as the type of biomaterial could have influenced the outcome of intervention.

It should be stressed that implant failures were only observed in heavy smokers (>20 cigarettes/day). Smokers carry a higher risk of implant failure with respect to non-smokers, especially

in the early healing phase after implant placement.^[12] One of the patients who experienced implant failure was also affected by hypertension (>135/80 mmHg) although, recent evidence indicates that this condition is not associated with a decrease in implant survival.^[13]

The present study does have its limitations. Firstly, it is a pilot case series which only includes a relatively small number of patients and short follow-up period. That said, similar pilot studies evaluating other sinus augmentation procedures have been conducted and published.^[14] Secondly, this case series does not directly compare mineralized bone allograft with other grafting materials. Such comparison may be conducted in a targeted clinical study, even if a direct analysis may be confounded by some bias. The present case series was completely conducted in a real-life scenario, without strict inclusion and exclusion criteria. It should be noted that clinical practice may represent a valuable source for robust and clinically-significant observations, including the evaluation of different materials. On this basis, our analysis may provide interesting preliminary findings on the effectiveness of homologous bone in the elevation of the sinus floor, which can be either confirmed or discarded in larger studies.

To sum up, the results of this preliminary case series suggest that the grafting of homologous bone followed by delayed implant placement may be a promising strategy for sinus augmentation. More prolonged and larger follow-up studies are needed to confirm this preliminary data. [Flow chart 1]

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How to cite this article: Aloja ED, Ricci M, Caso G, Santi E, Paolo T, Antono B, Covani U. The use of bone block allografts in sinus augmentation, followed by delayed implant placement: A case series. Contemp Clin Dent 2013;4:13-9.

Source of Support: Nil. **Conflict of Interest:** None declared.

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